DISTRICT OF COLUMBIA MUNICIPAL REGULATIONS for PHARMACEUTICAL DETAILERS

CHAPTER 83 PHARMACEUTICAL DETAILERS

8300 GENERAL PROVISIONS

8300.1 Effective, October 1, 2008, this chapter shall apply to applicants for and holders of a license to practice pharmaceutical detailing.

8300.2 Effective April 1, 2009, a person shall be licensed under the Act before the individual may practice pharmaceutical detailing in the District of Columbia.

8300.3 A person who practices pharmaceutical detailing in the District of Columbia without a license shall be subject to a fine of up to ten thousand dollars ($10,000.00) in addition to the other penalties and sanctions set forth in the Act and the HORA.

8300.4 Chapters 40 (Health Occupations: General Rules), and 41 (Health Occupations: Administrative Procedures) of this title shall supplement this chapter.

8300.5 For purposes of this chapter, an individual shall be deemed as engaging in the practice of pharmaceutical detailing if:

(a) He or she is acting as a representative of a pharmaceutical manufacturer or labeler; and

(b) Communicating in person with a licensed health professional or an employee or representative of a licensed health professional located in the District of Columbia;

(c) In a non-conference setting, as defined in this chapter;

(d) For the purpose of selling, marketing, or promoting a prescription or over-the-counter pharmaceutical product for use in humans, or providing information about a pharmaceutical product for the purpose of selling, marketing, or promoting such product.

8300.6 The scope of this chapter shall not apply to representatives who only sell, market, or promote veterinary drugs.

8300.7 The scope of this chapter shall not apply to the act of providing information about a pharmaceutical product solely for the purpose of conducting or pertaining to clinical trials, investigational drugs, or a Risk Evaluation and Mitigation Strategy pursuant to the Federal Food, Drug and Cosmetic Act.

8300.8 The scope of this chapter shall not apply to activities taking place at a conference, as defined in this chapter.

8300.9 The scope of this chapter shall not apply to health professionals participating in a conference, as defined in this chapter, including conferences targeting a local audience, solely as a speaker or presenter with respect to his or her area of expertise.

8301 TERM OF LICENSE

8301.1 Subject to § 8301.2, a license issued pursuant to this chapter shall expire at 12:00 midnight the last day of February of each even-numbered year.

8301.2 If the Director changes the renewal system pursuant to § 4006.3 of Chapter 40 of this title, a license issued pursuant to this chapter shall expire at 12:00 midnight of the last day of the month of the birth date of the holder of the license, or other date established by the Director.

8302 EDUCATIONAL REQUIREMENTS

8302.1 Except as otherwise provided in this chapter, an applicant shall furnish proof satisfactory to the Board that the applicant is a graduate of an institution of higher education recognized by the Board in accordance with § 742 of the Act, D. C. Official Code § 3-1207.42 (2001).

8302.2 Except as provided in § 8302.3, an applicant shall submit an official certificate of graduation or a transcript in a sealed envelope from the institution of higher education to the Board with the completed application.

8302.3 An applicant who holds a health professional license for a profession which requires a degree, may submit a copy of the license in lieu of an official certificate of graduation or transcript as proof of having graduated from an

institution of higher education recognized by the Board in accordance with § 742 of the Act, D. C. Official Code § 3-1207.42.

8302.4 The Board may grant a license to practice pharmaceutical detailing to an applicant who is a graduate of an institution of higher education from a foreign country, if the institution or education program was accredited by an accrediting body recognized by the Secretary of the United States Department of Education or the Council on Postsecondary Accreditation at the time the applicant graduated.

8302.5 If a document required by this chapter is in a language other than English, an applicant shall arrange for its translation into English by a translation service acceptable to the Board and shall submit a translation signed by the translator attesting to its accuracy.

8303 WAIVER OF EDUCATIONAL REQUIREMENTS

8303.1 Except as provided in § 8303.2, the Board shall waive the educational requirements set forth under § 8302.1 of this chapter for an applicant for licensure who can demonstrate to the satisfaction of the Board that he or she has been performing the functions of a pharmaceutical detailer as defined in § 8399 of this chapter on a full-time, or substantially full-time, basis for at least 12 months immediately preceding March 26, 2008.

8303.2 The Board may extend the waiver set forth in § 8303.1 up to an additional 12 months for an applicant who was on approved leave under the Family and Medical Leave Act or the District of Columbia Family Medical Leave Act for any portion of the 12 months immediately preceding March 26, 2008. The waiver may only be extended by the actual amount of leave taken by the applicant under the Acts up to an additional 12 months.

8303.3 To apply for a waiver of the educational requirements set forth under § 8302.1 of this chapter, an applicant shall:

(a) Submit a sworn statement attesting to the fact that the applicant has been performing the functions of a pharmaceutical detailer as defined in § 8399 of this chapter, for at least thirty-two (32) hours per week for at least twelve (12) months immediately preceding March 26, 2008, which shall include:

(1) The applicant's employers and contact information;

(2) The time period of practice;

(3) The name(s) and contact information of supervisor(s) or professional colleagues, as applicable; and

(4) A description of the applicant's duties; and

(b) Submit two (2) letters of attestation from current or previous supervisors who supervised the applicant's work in pharmaceutical detailing and who can attest to the fact that the applicant has been practicing as a pharmaceutical detailer for at least twelve (12) months. If the applicant does not have at least two (2) supervisors who can provide letters, applicant may submit one letter from a professional colleague who has first-hand knowledge that the applicant has been practicing as a pharmaceutical detailer for at least twelve (12) months.

8304 APPLICATION FOR LICENSURE

8304.1 To apply for a license, an applicant shall:

(a) Meet the education requirements set forth under § 8302 of this chapter or the requirements for waiver under § 8303 of this chapter;

(b) Submit a completed application to the Board on the required forms and include:

(1) The applicant's social security number on the application. If the applicant does not have a social security number, the applicant shall:

(i) Submit with the application a sworn affidavit, under penalty of perjury, stating that he or she does not have a social security number; and

(ii) Provide the Board with his or her social security information once a social security number has been obtained;

(2) Two (2) recent passport-type photographs of the applicant's face measuring two inches by two inches (2" x 2"), which clearly expose the area from the top of the forehead to the bottom of the chin; and

(3) One (1) clear photocopy of a U.S. government-issued photo ID, such as a driver's license, as proof of identity.

(c) Submit an official certificate of graduation or transcript in a sealed envelope from the educational institution(s) to the Board, which shall verify that the applicant meets the educational requirements set forth under § 8302 of this chapter;

(d) Submit a notarized statement to the Board that he or she understands and agrees to abide by the requirements for the practice of pharmaceutical detailing, including the code of ethics as set forth in § 8305;

(e) If applying by waiver, submit two (2) letters of recommendation meeting the requirements under § 8303 of this chapter; and

(f) Pay all required fees.

8304.2 The Board shall make a decision whether to approve or to initiate the process to deny an application for licensure within sixty (60) days after receipt of a completed application package containing all required materials, information, and supporting documents.

8304.3 If the Board initiates the process to deny an application, the Board shall send a written notice to the Applicant of the Board's decision to initiate the process within sixty (60) days. However, the formal denial process under the Administrative Procedures Act shall not be included within the sixty (60) day requirement.

8305 CODE OF ETHICS

8305.1 A pharmaceutical detailer shall not engage in any deceptive or misleading marketing of a pharmaceutical product, including the knowing concealment, suppression, omission, misleading representation, or misstatement of any material fact. Practices and conduct in compliance with the Food and Drug Administration's laws, regulations, policies and guidelines shall not be deemed a violation of this subsection.

8305.2 A pharmaceutical detailer shall not use a title or designation that might lead a licensed health professional, or an employee or representative of a licensed health professional, to believe that the pharmaceutical detailer is licensed to practice medicine, nursing, dentistry, optometry, pharmacy, or any other similar health occupation, in the District of Columbia, unless the pharmaceutical detailer holds an active license to practice that health occupation.

8305.3 A pharmaceutical detailer shall not attend patient examinations without the express, written consent of the patient.

8305.4 A pharmaceutical detailer shall not willfully harass, intimidate, or coerce a licensed health professional, or an employee or representative of a licensed health professional through any form of communication, including through the sending of messages of disappointment for the failure to prescribe certain medications.

8305.5 For purposes of § 8305.4, the Board shall use a reasonable person standard to determine whether the conduct constitutes willful harassment, intimidation, or coercion.

8305.6 A pharmaceutical detailer shall not continue to make sales calls upon a health professional, or an employee or representative of a health professional after the health professional prescriber has requested in writing to the pharmaceutical detailer or the detailer's employer not to receive any further sales calls.

8305.7 For purposes of § 8305.6, unless the person continuing to make the sales calls has actual knowledge of the request, a pharmaceutical manufacturer or labeler's employees and representatives will not be deemed to have knowledge of a health care provider's request until thirty (30) days after the health care provider submits the written request to the pharmaceutical detailer or his or her employer.

8305.8 A pharmaceutical detailer shall not offer a gift or remuneration of any kind to a member of a medication advisory committee; except that a pharmaceutical detailer may give medication samples to a member of a medication advisory committee that is also a licensed physician engaged in the practice of medicine.

8305.9 A pharmaceutical detailer shall not employ any inducement or misleading statements to gain access to a healthcare professional.

8305.10 A pharmaceutical detailer shall provide information to healthcare professionals That is accurate and fairly balanced in compliance with FDA policy and practices on the provision of information to health care professionals. However, nothing in this section shall be construed to require a pharmaceutical detailer to promote a competitor's product.

8305.11 In addition to the regulations set forth under this section, any holder of a license under this chapter or any person authorized to practice pharmaceutical detailing functions under this chapter shall comply with the standards of ethical and professional conduct established by the Pharmaceutical Research and Manufacturers of America (PhRMA) in its publication entitled "PhRMA Code on Interactions With Healthcare Professionals" as it may be amended or republished from time to time. Where there is a conflict between this publication and the regulations set forth in this Chapter or the provisions of the Act, the regulations and/or Act shall control.

8306 CONTINUING EDUCATION REQUIREMENTS

8306.1 This section shall apply to applicants for the renewal, reactivation, or reinstatement of a license.

8306.2 A continuing education credit shall be valid only if it is part of a program or activity approved by the Board in accordance with § 8307 of this chapter.

8306.3 An applicant for renewal of a license shall:

(a) Have completed a minimum of fifteen (15) contact hours of approved continuing education credit during the two (2) year period preceding the date the license expires, which, beginning with the renewal period ending February 28, 2020, shall include at least two (2) hours of continuing education on cultural competency or specialized clinical training focusing on patients or clients who identify as lesbian, gay, bisexual, transgender, gender nonconforming, queer, or question their sexual orientation or gender identity and expression ("LGBTQ") meeting the requirements of D.C. Official Code § 3-1205.10(b)(5);

(b) Attest to completion of the required continuing education credits on the renewal application form; and

(c) Be subject to a random audit.

8306.4 To qualify for a license, a person in inactive status within the meaning of § 511 of the Act (D.C. Official Code § 3-1205.11) who submits an application to reactivate a license shall submit proof, pursuant to § 8306.6, of having completed fifteen (15) hours of approved continuing education credit, which, beginning with the licensure period ending February 28, 2020, shall include at least two (2) hours of continuing education on cultural competency or specialized clinical training focusing on patients or clients who identify as lesbian, gay, bisexual, transgender, gender nonconforming, queer, or question their sexual orientation or gender identity and expression ("LGBTQ") meeting the requirements of D.C. Official Code § 3-1205.10(b)(5), obtained within the two (2) year period preceding the date of the application for reactivation of that applicant's license, and an additional eight (8) hours of approved continuing education credit for each additional year that the applicant was in inactive status beginning with the third year.

8306.5 To qualify for a license, an applicant for reinstatement of a license shall submit proof, pursuant to § 8306.6, of having completed fifteen (15) hours of approved continuing education credit, which, beginning with the licensure period ending February 28, 2020, shall include at least two (2) hours of continuing education on cultural competency or specialized clinical training focusing on patients or clients who identify as lesbian, gay, bisexual, transgender, gender nonconforming, queer, or question their sexual orientation or gender identity and expression ("LGBTQ") meeting the requirements of D.C. Official Code § 3-1205.10(b)(5), obtained within the two (2) year period preceding the date of the application for reinstatement of the applicant's license, and an additional eight (8) hours of approved continuing education credit for each additional year that the license was expired beginning with the third year.

8306.6 Except as provided in § 8306.8, an applicant under this section shall prove

completion of required continuing education credits by submitting with the application the following information with respect to each program:

(a) The name and address of the sponsor of the program;

(b) The name of the program, its location, a description of the subject matter covered, and the names of the instructors;

(c) The dates on which the applicant attended the program;

(d) The hours of credit claimed; and

(e) Verification by the sponsor of completion, by signature or stamp.

8306.7 Beginning with the 2010 renewal period, the Board shall conduct a random audit of continuing education credits at the completion of each renewal period.

8306.8 Applicants for renewal of a license shall only be required to prove completion of the required continuing education credits by submitting proof pursuant to § 8603.6 if requested to do so as part of the random audit, or if otherwise requested to do so by the Board.

8306.9 An applicant for renewal of a license who fails to renew the license by the date the license expires may renew the license for up to sixty (60) days after the date of expiration by completing the application, submitting the required supporting documents, and paying the required additional late fee. Upon renewal, the applicant shall be deemed to have possessed a valid license during the period between the expiration of the license and the renewal thereof.

8306.10 If an applicant for renewal of a license fails to renew the license and pay the late fee within sixty (60) days after the expiration of applicant's license, the license shall be considered to have lapsed on the date of expiration. The applicant shall thereafter be required to apply for reinstatement of an expired license and meet all requirements and fees for reinstatement.

8306.11 The Board may, in its discretion, grant an extension of the sixty (60) day period to renew after expiration if the applicant's failure to renew was for good cause. As used in this section, "good cause" includes the following:

(a) Serious and protracted illness of the applicant; and

(b) The death or serious and protracted illness of a member of the applicant's immediate family.

8306.12 An extension granted under this section shall not exempt the licensee from complying with the continuing education requirements for any other renewal

period.

8307 APPROVED CONTINUING EDUCATION PROGRAMS

8307.1 The Board may, in its discretion, approve continuing education programs that contribute to the growth of an applicant in professional competence in the practice of pharmaceutical detailing and which meet the other requirements of this section.

8307.2 The Board may approve continuing education programs that meet the requirements of § 8307.3 and provide instruction in one of the following subjects:

(a) General medical and pharmaceutical terminology and abbreviations;

(b) Food and Drug Administration laws and regulations pertaining to drug marketing, labeling, and clinical trials;

(c) The cost-effectiveness of pharmacological treatments;

(d) Therapeutic drug classes and categories;

(e) Professional ethics;

(f) Properties and actions of drugs and drug delivery mechanisms;

(g) Etiologies, characteristics, and therapeutics of disease states;

(h) Pharmacology; and

(i) The anatomical and physiological effect of pharmaceuticals.

8307.3 To qualify for approval by the Board, a continuing education program shall be an educational program given at a conference, a lecture, seminar, course of instruction, workshop, or on the Internet, and be prepared, offered, or administered by one of the following:

(a) A nationally or locally accredited program provider;

(b) A governmental unit;

(c) A health care facility;

(d) A pharmaceutical company; or

(e) An institution of higher learning recognized by an accrediting body approved by the Secretary of the United States Department of Education.

8307.4 The Board may issue a list of approved continuing education programs.

8307.5 An applicant shall have the burden of verifying whether a program is approved by the Board pursuant to this section prior to attending the program.

8307.6 The Board may approve the following continuing education activities by an applicant:

(a) Serving as an instructor or speaker at a lecture, conference, seminar, workshop, course of instruction, or in-service training; and

(b) Publication of an article or book review in a professional journal or bulletin or publication of a book or chapter in a book.

8308 CONTINUING EDUCATION CREDITS

8308.1 A minimum of fifty (50) minutes shall constitute one (1) contact hour.

8308.2 For approved undergraduate courses, each semester hour of credit shall constitute fifteen (15) contact hours of continuing education credit.

8308.3 The Board may grant credit to an applicant who serves as an instructor or speaker at an acceptable program for both preparation and presentation time, subject to the following restrictions:

(a) The maximum amount of credit which may be granted for preparation time shall be twice the amount of the associated presentation time; and

(b) The maximum amount of credit which may be granted pursuant to this subsection shall be fifty percent (50%) of an applicant's continuing education requirement; and

(c) The presentation shall have been completed during the period for which credit is claimed.

8308.4 The Board may grant an applicant who is an author or editor of a published book fifteen (15) continuing education credits, if the book has been published or accepted for publication during the period for which credit is claimed, and the applicant submits proof of this fact in the application.

8308.5 The Board may grant an applicant who is an author of a published original paper five (5) continuing education credits, subject to the same restrictions set forth for books in § 8308.4.

8308.6 The Board may grant an applicant who is the sole author of a published book review, review paper, or abstract, two (2) continuing education credits, subject to the same restrictions set forth for books in § 8308.4.

8309 AUTHORITY TO COLLECT INFORMATION AND RECORD RETENTION

8309.1 In carrying out its functions under the Act, the Board of Pharmacy and an agent acting on its behalf is authorized to collect information from licensed pharmaceutical detailers relating to their communications with licensed health professionals, or with employees or representatives of licensed health professionals, located in the District.

8309.2 Upon receipt of a verbal or written request by the Board or its agent for information pursuant to § 8309.1 of this chapter, a pharmaceutical detailer shall provide the requested information within ten (10) business days of the request.

8309.3 Refusal by a pharmaceutical detailer to provide the requested information with the time allotted shall constitute a basis for disciplinary action under the Health Occupations Revision Act of 1985, effective march 25, 1986 (D.C. Law 6-99; D.C. Official Code § 3-1201.01 *et seq.*)

8309.4 A pharmaceutical detailer shall retain documents and information relating to his or her communications with licensed health professionals, or with employees or representatives of licensed health professionals, located in the District for a period of five years from the date of the communication or contact.

8309.5 Within ten (10) days of leaving the employ of a pharmaceutical company, a pharmaceutical detailer shall provide written notification to the Board of his or her departure and the name, address, email, and telephone number of the person within the company who may be contacted for retrieving the records required to be maintained under this chapter.

8309.6 For purposes of complying with this section, a pharmaceutical detailer shall maintain documents and information relating to his or her communications with licensed health professionals or with employees or representatives of licensed health professionals that include but are not limited to:

(a) The name, business address, and telephone number of the healthcare professional the detailer visited;

(b) The date, time and location of the visit:

(c) The products discussed;

(d) Whether samples were provided; and

(e) The type of materials provided to the health care professional, if applicable.

8310 LICENSURE AND RENEWAL FEES

8310.1 The fees related to pharmaceutical detailers are as follows:

(a) Initial license fee	$175.00
(b) Biennial renewal fee	$165.00
(c) Late fee	$85.00
(d) Duplicate certificate	$34.00
(e) License verification	$34.00

8311 SUPERVISED PRACTICE

8311.1 An applicant for a pharmaceutical detailer license may engage in the supervised practice of pharmaceutical detailing under the supervision of a licensed pharmaceutical detailer for a period not to exceed sixty (60) days under the following conditions:

(a) The applicant has an initial application for licensure pending before the Board;

(b) Has received a supervised practice letter from the Board; and

(c) Has not previously received a supervised practice letter from the Board.

8311.2 The supervising pharmaceutical detailer shall be fully responsible for the supervised practice of the supervisee during the period of supervision, and is subject to disciplinary action for any violation of the Act or this chapter by the person being supervised.

8311.3 A supervisee shall be subject to all applicable provisions of the Act and this chapter.

8311.4 If the Board finds that a person practicing under supervision has violated the Act or this title, the Board may, in addition to any other disciplinary actions permitted by the Act, deny, revoke, suspend, or restrict the privilege of the supervisee to practice.

8399 DEFINITIONS

8399.1 As used in this Chapter the following terms shall have the meanings ascribed:

Act- SafeRx Amendment Act of 2008, effective March 26, 2008 (D.C. Law 17-0131; 55 DCR 4462, published on April 25, 2008 (the Act), and Mayor's Order Mayor's Order 2008-94, dated July 3, 2008.

Applicant – A person applying for a license to practice pharmaceutical detailing under this chapter.

Board – the Board of Pharmacy, established by § 208 of the Act, D.C. Official Code § 3-1202.08.

Conference - (1) A meeting, symposium, exposition, exhibit, convention, assembly, or like gathering, including meetings of a regional, national, or international professional association, society, or body, for the discussion of health-related issues consisting of multi-pharmaceutical company or labeler representation and targeting a regional, national, or international audience; or (2) a scientific or medical educational meeting or symposium that is accredited by a nationally recognized healthcare professional education accreditation body (e.g., the Accreditation Council for Continuing Medical Education, the Accreditation Council for Pharmacy Education, and the American Nurses Association).

Department- Department of Health

Director- Director of the Department

District of Columbia Family Medical Leave Act- District of Columbia Family Medical Leave Act of 1990, effective October 3, 1990 (D.C. Law 8-181; D.C. Official Code § 32-501 et seq.)

Family Medical Leave Act- Family Medical Leave Act of 1993, approved February 5, 1993 (107 Stat. 7; 29 U.S.C. § 2601 *et seq.*)

FDA- the federal Food and Drug Administration

HORA- Health Occupations Revision Act of 1985, effective March 25, 1986 (D.C. Law 6-99; D.C. Official Code § 3-1201.01 *et seq.*)

Institution of Higher Education- as defined in § 101 of the Higher Education Act of 1965, as amended, approved October 7, 1998 (112 Stat. 1581; 20 U.S.C. § 1001).

Labeler- An entity or person that receives pharmaceutical products from a manufacturer or wholesaler and repackages those pharmaceuticals for later retail sale and that has a labeler code from the federal Food and Drug Administration under 21 C.F.R. § 207.20.

Manufacturer- a manufacturer of pharmaceutical products and includes subsidiary or affiliate of a manufacturer.

Medication Advisory Committee- any committee or panel that is responsible for making recommendations or decisions regarding a formulary to be used by a health program administered by the government of the District of Columbia.

Multi-pharmaceutical or labeler representation- at least three or more pharmaceutical companies or labelers which shall not be subsidiaries, or affiliations of the same company or parent company.

Pharmaceutical Company- any entity that is engaged in, either directly or indirectly, the production, preparation, propagation, compounding, manufacturing, conversion or processing of a drug or biologic product, including any person acting as its agent or representative.

Pharmaceutical Detailer: a person licensed under the Act to engage in the practice of pharmaceutical detailing.

Pharmaceutical Product- a drug or biologic regulated by the federal Food and Drug Administration.

Practice of Pharmaceutical detailing- the practice by a representative of a pharmaceutical manufacturer or labeler of communicating in person with a licensed health professional, or an employee or representative of a licensed health professional, located in the District of Columbia, for the purpose of selling, providing information about, or in any way promoting a pharmaceutical product.

Sales Call- any in person communication with a health care professional or his or her employees or representatives for the direct purpose of selling marketing, or promoting a pharmaceutical product, or providing information about a pharmaceutical product for the purpose of selling, marketing, or promoting such pharmaceutical product on behalf of a pharmaceutical manufacturer or labeler.